

Message Text

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PAGE 01 STATE 075390
ORIGIN HEW-06

INFO OCT-01 AF-10 ARA-14 EUR-12 EA-12 NEA-10 ISO-00
OES-07 SIG-03 MMO-04 EB-08 COME-00 /087 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: REVANS
EA/PRCM:MBRIESEN(INFO)
NEA/INS:ATHIBAULT(INFO)
EA/J:EFEATHERSTONE(INFO)
ARA/MEX:GFALK(INFO)
NEA/ARN:LPOPE(INFO)
AF/S:JTAYLOR(INFO)
EUR/EE:DJOHNSON(INFO)
EUR/NE: WNEWLIN (INFO)
EA/ANP: TWAJDA (INFO)

-----116181 240745Z /11

P 232103Z MAR 78
FM SECSTATE WASHDC
TO AMCONSUL HONG KONG PRIORITY
AMEMBASSY TEL AVIV PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY BEIRUT PRIORITY
AMEMBASSY MEXICO PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY TAIPEI PRIORITY
AMEMBASSY BELGRADE PRIORITY
AMEMBASSY CANBERRA PRIORITY
AMEMBASSY THE HAGUE PRIORITY

UNCLAS STATE 075390

E.O. 11652:N/A

TAGS: OGEN, ETRD, EIND, TBIO, HK, IS, JA, LE, MX, SF, TW,
YP, AS, NL
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SUBJECT: FDA ADVISORY - UNSTERILE MEDICAL DEVICE (RECALL
T-056-8)

1. FDA ADVISES OF THE FOLLOWING RECALL:
PRODUCT INVOLVED: MCLAUGHLIN DUO-CATH 3CM CATHETER CANNULA
FOR SINGLE PUNCTURE HEMODIALYSIS, IN 50 OR 200 COUNT CARD-

BOARD CONTAINERS.

PRODUCT IDENTIFICATION: LABEL IDENTIFICATION READS IN PART
"ONE EACH MCLAUGHLIN DUO-CATH; 3CM; CATHETER/CANNULA FOR
SINGLE PUNCTURE HEMODIALYSIS; STERILE; CONTENTS OF UN-
OPENED AND UNDAMAGED PACKAGE ARE STERILE; MANUFACTURED BY;
MEDICAL DEVICE LABORATORIES, INC 3198-M AIRPORT LOOP
DRIVE COSTA MESA, CALIFORNIA.
MANUFACTURER/RECALLING FIRM: MEDICAL DEVICE LABORATORIES,
INC., 3198-M AIRPORT LOOP DRIVE, COSTA MESA, CALIFORNIA,
92626.

2. REASON FOR RECALL: THE PRODUCT IS BEING RECALLED DUE
TO STERILITY FAILURE. THE FIRM REPORTS THAT THE PARENT
FIRM'S LABORATORY HAS FOUND GRAM POSITIVE RODS TO BE THE
CONTAMINANTS. THE FIRM FIRST BECAME AWARE OF A PROBLEM
WITH THE PRODUCT UPON RECEIVING A VERBAL COMPLAINT FROM
BIO MEDICAL APPLICATIONS, 340L MARKET STREET, PHILADELPHIA,

PENNSYLVANIA (A DIALYSIS CLINIC). THE COMPLAINT CONCERNED
THREE PATIENTSWHO DEVELOPEDWOUND ABSESSES AFTER USE OF
THE PRODUCT. RECALL INITIATED 12/30/77.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE BEEN ADVISED OF RECALL. ANY
QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD BE
REFERRED TO FIRM. CONTACT PERSON FOR RECALL IS:
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WILLIAM F. MCLAUGHLIN, PRESIDENT, MEDICAL DEVICE LABOR-
ATORIES, INC., 3198-M AIRPORT LOOP DRIVE, COSTA MESA,
CALIFORNIA; TELEPHONE NO. 714-556-1905; TWX NO. 910/5951982

4. FOREIGN CONSIGNEES AS FOLLOWS:

CORDIS DOW	SURGIPROD
1805 GAMMON HOUSE	32 DE VILLE STREET
12 HARCOURT RD.	LANGLAAGTE
HONG KONG B.C.C.	P.O. BOX 600118
(BRIT. CROWN COLONY)	JOHANNSBURG
--	S. AFRICA

SCHMIDT AND CO. LTD.	D.J. WINTERS CO.
39TH FLOOR	P.O. BOX 53 319
CONNAUGHT CENTER	TAIPEI, TAWAIN
GPO BOX 297	REPUBLIC OF CHINA
HONG KONG B.C.C.	

MEDTECHNICA LTD.	SALUS
P.O. BOX 2695	61001 LJUBLAJANA
TEL-AVIV, ISRAEL	TITOVA, CESTA 50

-- YUGOSLAVIA
AIKA ICHIKAWA SHISEIDO, INC.
15-9 HONGO 3-CHOME EUROSPITAL
BUNKYO-DU S.P.A. 34147
TOKYO, JAPAN TRIESTE, VIA FLAVIA,
-- 122 ITALY
EMERS CO. LTD.
ZINNOSHINDIV CHO DOMMEDICA PTY, LTD.
TOYOHASHI, JAPAN 5 SIRIUS RD.
-- N.S.W. 2066
MIYANO MEDICAL INSTRUMENTS AUSTRALIA
IKUTA-DU
IOHE 650 JAPAN ORGANON TEKNIKA B.V.
INDUSTRIELAAN 84
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TAKEDA CHEM. IND. 4202 OSS
KIGOSH-KU HOLLAND
OSAKA 541
JAPAN

MECRESCO CORPORACION GETZ
DR. A. SHAMI BLDG. 23-70 PISO
HANRA ST RIO GUARDIANA
BEIRUT, LEBANON MEXICO 5 D.F. VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALLS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 23 mar 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE075390
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VB
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780129-1259
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780330/aaaaazpx.tel
Line Count: 145
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 531338be-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3221264
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - UNSTERILE MEDICAL DEVICE (RECALL T-056-8)
TAGS: OGEN, ETRD, EIND, TBIO, HK, IS, JA, LE, MX, SF, TW
To: HONG KONG TEL AVIV MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/531338be-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014